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EXAMINER	
HOPKINS, CHRISTINE D	

ART UNIT	PAPER NUMBER
3735	

DATE MAILED: 10/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,782	PEDERSEN ET AL.	
	Examiner	Art Unit	
	Christine D. Hopkins	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *07 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed August 7, 2006. Claims 1-28 are now pending. The Examiner acknowledges amendments to claims 1, 18, 22 and 25.

Specification

2. The disclosure is objected to because of the following informalities: at page 1, "benefit of priority from" should read --benefit of--.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-11 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steele, Sr. et al. (U.S. Patent No. 6,572,527) in view of Rapacki et al. (U.S. Pub. No. 2004/0060563). Steele, Sr. et al (hereinafter Steele) discloses a radioactive seed-holding system for application in a brachytherapy procedure. Rapacki et al. (hereinafter Rapacki) disclose a flow control device that includes a sealing component for preventing fluid flow when used with, in particular, a brachytherapy device. With reference to claim 1, Steele teaches a seed-holding system **10** that comprises a transfer device **46** which defines a channel comprising a proximal end and

a distal end (col. 2, lines 60-67) where seeds are dispensed to a typical applicator through an applicator bore **98**, and into an implantation needle (col. 7, lines 12-17 and Fig. 7). However, Steele does not teach a septum located within a channel of the device. Rapacki teaches a flow control device containing a septum **630** for passing objects, such as brachytherapy sources, to a body cavity while simultaneously controlling the flow of bodily fluids ([0166] and [0342]). Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have modified the device of Steele to have a septum as taught by Rapacki, located within the channel of the applicator bore **98** of Steele for allowing the passage of brachytherapy sources, yet preventing bodily fluids from entering and consequently contaminating the device from a cavity within the patient benefiting from the treatment.

With respect to claim 2, the septum **630**, as taught by Rapacki, is made of a deformable elastic material [0151]. In view of claim 3, Rapacki teaches that the elastomeric material being used may be comprised of silicone [0175].

With respect to claim 4, Steele teaches a device, comprising two components, both components being made of plastic (col. 2, lines 23-26). In reference to claim 5, any chuck can be made "disposable," however the seed-holding system of Steele provides for a holder **12** which may be disposable (col. 2, lines 4-5).

In regards to claim 6, the transfer device of Steele (containing the channel as previously mentioned) can contain metal to provide radiation shielding (col. 5, lines 1-2).

With respect to claim 7, the holder **12** of Steele is the "magazine well" which holds the seeds to be delivered, and the transfer device **46** is coupled to or acts to

retain the seed holder **12**, thus serving as a "seed magazine retention structure" (col. 3, lines 16-20).

In reference to claims 8-10, Steele describes that a pusher assembly **54** (Figs. 2 and 3), to include a push disk **80**, can be located at the proximal end of the main housing **48**, to function as an "insert" to the housing (col. 6, lines 20-22 and Fig. 2). The push disk, and other immediately surrounding components to comprise the "insert" can be made of any material (e.g., metal or plastic). Refer to col. 6, lines 33-36 and Fig. 3.

With regards to claim 11, the "insert" or pusher assembly of Steele, located at the proximal end, contains a push disk **80** that has a diameter complementary, or "essentially the same as," that of the distal end in order to facilitate insertion into the housing **48** (Fig. 3).

With reference to claims 15-17, Steele discloses a transfer device **46** or "seed magazine retaining structure" to enclose the "seed magazine," or holder **12** of Fig. 1 (see rejection supra regarding claim 7). With reference to the "cantilever" of claim 16, the apparatus of Steele comprises a "sleeve-like cavity" **16** (Fig. 3) that is a projecting structure, or "cantilever" which contains the seed holder **12**. Fig. 3 depicts the removal of this assembly, while Fig. 2 demonstrates this projecting structure bearing the load of the radioactive seeds, thus serving as a "cantilever" (col. 3, lines 32-51). With regards to claim 17, the "protrusion" or sleeve-like cavity of Steele engages the seed holder **12** or "seed magazine" (col. 3, lines 32-51 and Figs. 2-3).

With respect to claim 18, Steele discloses a transfer device **46** or "chuck housing" and a holder **12** or "chuck" for the delivery of radioactive seeds, with the

"chuck" comprising a proximal and distal end, and a channel extending therebetween (Fig. 1). The "chuck" or holder can contain a needle (col. 1, lines 46-48) and is engaged by the "chuck housing" or transfer device via elements 26 and 28, the disk protrusions (Figs. 4A and 4B), which act to couple the two components (col. 3, lines 60-61). However, Steele does not teach a septum located within a channel of the device. Rapacki teaches a flow control device containing a septum **630** for passing objects, such as brachytherapy sources, to a body cavity while simultaneously controlling the flow of bodily fluids ([0166] and [0342]). Further, Steele teaches a push rod or stylet that moves back and forth through the applicator bore **98** to push seeds into an implantation needle for subsequently dispensing into a body cavity (col. 7, lines 9-24). Placement of a septum within the channel of the applicator bore **98** will prevent any bodily fluids stemming from the patient from entering the applicator and seed-holding system. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have modified the device of Steele to have a septum as taught by Rapacki, located within the channel of an applicator bore **98** similar to that of Steele for allowing the passage of brachytherapy sources, yet preventing bodily fluids from entering and consequently contaminating the device from a cavity within the patient benefiting from the treatment.

5. Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steele, Sr. et al. (U.S. Patent No. 6,572,527) in view of Rapacki et al. (U.S. Pub. No. 2004/0060563) as applied to claim 1 above, and further in view of Cook (U.S. Pub No. 2002/0107483). The combination of Steele and Rapacki disclose the invention as

claimed, see rejection supra; however the combination does not teach vents to permit the exit of air or contaminants from the device. Cook discloses a piercing system for the delivery of a material to a patient geared towards reducing the amount of contaminants introduced back into the system from the patient's body. With reference to claim 12, Cook teaches a vent **74** that allows air to escape from a housing **54** comprising a cavity **62** or "channel" and fluids withdrawn through the needle tip to escape and be contained within the vent [0040]. With respect to claims 13 and 14, the invention of Cook comprises a chamber when the vent is capped (preventing egress of fluids) with **91** of Fig. 4, thus defining a "reservoir" where air is permitted to exit the "channel" or cavity **62** of the invention and completely exit the invention from this "reservoir" ([0040] and [0042], in addition to Fig. 4). The device of Steele incorporates an applicator bore **98**, defining a "channel" which leads to the bore end **30** (Fig. 7) where a seed is deposited for transfer to a needle, and subsequently the patient. The vent of Cook is capable of being attached to, or notched into (as in Fig. 4 of Cook) the "channel" or end of the applicator bore of Steele where the needle is to be injected to allow any air or contaminants received from the body of the patient to escape prior to retraction back into the applicator **96** (Fig. 7 of Steele). The vent of Cook also may be adapted to the "channel" of Steele to comprise a vent cap, thus defining an enclosure, or "reservoir." The air and contaminants resulting from the needle in the applicator bore **98** of Steele will be permitted to enter this "reservoir" including a vent cap, to complete this chamber or "reservoir" and exit the instrument if in a gaseous state, such as air. Moreover, at the time of the invention it would have been obvious for one of ordinary skill in the art to

have made the device of the Steele/Rapacki combination to include a vent, chamber and vent cap as taught by Cook to allow air or contaminants to escape the instrument, thus preventing them from entering the medical device.

6. Claims 18-23 are rejected under 35 U.S.C. 103(a) as being obvious over Pedersen (U.S. Pub. No. 6,656,107) in view of Rapacki et al. (U.S. Pub. No. 2004/0060563). The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

With respect to claim 18, the applicator chuck of Pedersen comprises a "chuck" **22**, defining two ends (distal and proximal) forming a channel. In the instance of one particular embodiment, Pedersen teaches a "cylindrical chuck" (col. 5, lines 62-67 and

col. 6, lines 1-3). With respect to the "needle," the invention of Pedersen discloses a chuck for releasably holding a needle (col. 4, lines 30-31). In reference to the "chuck housing configured to engage said chuck," the housing so claimed may contain at least part of the seed magazine, hence the slot **30** of Pedersen contains the seed magazine, comprising a side surface **32**, second side surface **34**, and back surface **36**, thus constituting a "housing" (col. 5, lines 62-65 and col. 6, lines 4-6). However, Pedersen does not teach a septum contained within the channel of the device. Rapacki teaches a flow control device containing a septum **630** for passing objects, such as brachytherapy sources, to a body cavity while simultaneously controlling the flow of bodily fluids ([0166] and [0342]). Moreover, a stylet can be pushed through the chuck **22** to push a seed from the seed magazine into the needle for implantation. Thus, a septum placed over the opening at the distal end (see Fig. 2) of the chuck will prevent any bodily fluids during a brachytherapy procedure from entering the device when the stylet retracts from pushing a seed into the implantation needle. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have modified the invention of Pedersen to incorporate a septum similar to that as taught by Rapacki such that egress of bodily fluids into the chuck of Pedersen is prevented upon retraction of the stylet following seed placement.

With respect to claims 19-20, the leaf spring **250** disclosed by Pedersen (Fig. 13), or "insert" located at the proximal end of the chuck **258**, connects the chuck and the "chuck housing" or slot **30** via a screw **265** that extends through a screw opening **268** to come in contact with the leaf spring or "insert." In reference to claim 20, the screw

opening **268** extends from an exterior surface to the "channel" or slot **30** of the chuck **258** to come in contact with the "insert" or leaf spring, which attaches the two components via a screw **265**, or other suitable means. In reference to claim 21, the "insert" or leaf spring **250** is in direct contact with the "chuck housing" or slot **260** by way of a screw (col. 8, lines 50-63, and Fig. 13).

In regards to claims 22 and 23, the "chuck connection device," as taught by Pedersen, comprises a structure **40** (Fig. 3) that can protrude from the back surface of the slot **30**, or "chuck housing" to connect it to the chuck, thus constituting a "chuck connection device." This structure, containing a spring, can have two openings, to be "distal" and "proximal" portions. Furthermore, the structure acts to engage and retain, or lock, an object placed within the slot (col. 6, lines 14-25).

7. Claim 24 is rejected under 35 U.S.C. 103(a) as being obvious over Pedersen (U.S. Patent No. 6,656,107) in view of Rapacki et al. (U.S. Pub. No. 2004/0060563) and further in view of Steele (U.S. Patent No. 6,572,527). The applied reference has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or

declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The combination of Pedersen and Rapacki discloses the invention as claimed, see rejection supra; however the combination does not teach a device for retaining a radiation shield. The examiner notes that any device can be "configured to" retain a radiation shield. Steele discloses a radioactive seed-holding system for application in a brachytherapy procedure to further include a shield to provide radioactive shielding around the seed holder. In reference to claim 24, the "chuck connection device" of Pedersen comprises a structure **40** of Fig. 3, that can protrude from the back surface of the slot **30**, or "chuck housing" to connect it to the chuck, thus constituting a "chuck connection device." Moreover, this slot receives the seed holder thus comprising a "shield" around the holder, further rendering it capable of providing radiation shielding (col. 8, lines 50-63, and Fig. 13 of Pedersen). Therefore, at the time of the invention it would have been obvious for one of ordinary skill in the art to have made the "chuck connection" device of the Pedersen/Rapacki combination to include radiation shielding as taught by Steele to provide shielding around the holder which contains the seeds to be dispensed to reduce the risk of radiation exposure to medical staff (col, 2, lines 9-11 of Steele).

8. Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fontayne (U.S. Patent No. 6,629,960 in view of Rapacki et al. (U.S. Pub. No. 2004/0060563). Fontayne discloses a medical instrument, containing a needle hub assembly, for delivery of radioactive seeds to a patient's body. With respect to claim 25, Fontayne teaches an instrument, or "applicator" of radioactive seeds, composed of a proximal and distal end (col. 6, lines 41-44), thus defining a "channel," and a needle hub **1220** (Fig. 13), comprising a needle release arm retention slot **1330** or "needle retention member" to retain the needle within the instrument (col. 2, lines 45-49 and col. 9, lines 44-49). However, Fontayne does not teach a septum located within a channel of the device. Rapacki teaches a flow control device containing a septum **630** for passing objects, such as brachytherapy sources, to a body cavity while simultaneously controlling the flow of bodily fluids ([0166] and [0342]). Seed placement results from a stylet **2410** pushing a seed **2420** to the distal end **772** of the needle **770** whereby it is subsequently pushed into a patient's tissue (col. 12, lines 66-67 - col. 13, lines 1-7). A septum positioned within this "channel" will prevent contamination to the instrument such that when the needle is retracted for acceptance of another seed, blood or other bodily fluids are wiped from the needle. Therefore, at the time of the invention it would have been obvious to one having ordinary skill in the art to have fitted an instrument similar to that of Fontayne with a septum as taught by Rapacki in the channel formed for seed placement so that any fluid contact with the patient would not contaminate the instrument.

Regarding claims 26-28, the "needle retention member" or needle hub assembly, as taught by Fontayne, comprises a needle release arm **1810**, or "flex beam," capable of being in a down position, hence its ability to "flex." The assembly also includes an actuation cam, or "actuator" **1814** and a needle release arm **1819**, or "pivot structure" that pivots about a pivot point **1815** (col. 15, lines 36-46 and Figs. 18-19). With reference to claim 27, the needle release arm is shown in the down position in Fig. 18, thus helping to hold the needle assembly in place, and thereby also exerting a "force" against the needle (col. 15, lines 38-31). The needle release arm **1810** or "flex beam" of Fontayne raises up about a pivot point out of the needle retention slot **1330**, thus releasing itself of the stress incurred upon placement into this slot when holding the needle assembly **1225** for separation from the medical instrument (col. 15, lines 36-50 and Figs. 18-19).

Response to Arguments

9. Applicant's arguments filed August 7, 2006 with regard to correction of the specification has been fully considered but is not persuasive.

10. Applicant's arguments filed August 7, 2006 with regard to claim rejections under 35 USC 112, second paragraph, have been fully considered and are persuasive. The rejection of claims 2-3 and 22-24 under 35 USC 112, second paragraph, has been withdrawn.

11. Applicant's arguments filed August 7, 2006 with respect to the rejection of claims 1, 4-11, 15-18 and 22-24 under US 102(e) citing Steele et al. ('527) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Steele et al. in view of Rapacki (2004/0060563). Applicant contends that the Steele reference does not teach a "septum," however the original claims only required that a chuck be "adapted to" contain a septum, thus not necessitating the inclusion of such.

12. Applicant's arguments filed August 7, 2006 with respect to the rejection of claims 1 and 4-23 under US 102(e) citing Pedersen et al. ('107) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Steele et al. in view of Rapacki (2004/0060563), Steele et al. in view of Rapacki and further in view of Cook (2002/0107483), and Rapacki in view of Pedersen et al. ('107).

13. Applicant's arguments filed August 7, 2006 with respect to the rejection of claims 1, 4-9, 11, 15-17 and 25-28 under US 102(e) citing Fontayne ('960) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Steele et al. in view of Rapacki, and Fontayne in view of Rapacki.

14. Applicant's arguments filed August 7, 2006 with respect to the rejection of claims 2-3 under US 103(a) citing Steele et al. ('527) in view of Matsuura et al. ('461) have

been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Steele et al. in view of Rapacki.

15. Applicant's arguments filed August 7, 2006 with respect to the rejection of claims 12-14 under US 103(a) citing Steele et al. ('527) in view of Cook (2002/0107483) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Steele et al. in view of Rapacki and further in view of Cook.

16. Applicant's arguments filed August 7, 2006 with respect to the rejection of claim 24 under US 103(a) citing Pedersen et al. ('107) in view of Steele ('527) have been fully considered but are moot in view of the new grounds of the rejection set forth above, citing Pedersen in view of Rapacki and further in view of Steele.

17. Applicant's arguments filed August 7, 2006 with respect to the double patenting rejection of claim 1 citing Pedersen et al. ('107) have been fully considered and are persuasive.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine D. Hopkins whose telephone number is (571) 272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CDH

Christine D Hopkins
Examiner
Art Unit 3735

Charles A Marmor, II
SPE, Art Unit 3735